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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/960,389 | 09/24/2001 | Mark Ashby | 034298-120 | 7856 |

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01/20/2004

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| EXAMINER |
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BAXTER, JESSICA R

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| ART UNIT | PAPER NUMBER |
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3731

DATE MAILED: 01/20/2004

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/960,389

Applicant(s)

ASHBY ET AL.

Examiner

Jessica R Baxter

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 September 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 97/28746 to Burney et al.

Burney discloses a system comprising a catheter with a closed distal end (tip 30) and a side port (lateral opening 24) adjacent the distal end and an adaptor (needle hub 17) connected to the catheter having a tapered lumen with a large diameter proximal end and a small diameter distal end, wherein the small diameter distal end is connected to the catheter, and wherein the adaptor is removable from the catheter (page 16 lines 20-25).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 3-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 97/28746 to Burney et al. (Burney) in view of U.S. Patent No 5,775,333 to Burbank et al.

Burney discloses the claimed invention except for the biopsy cannula having a tissue puncturing distal end and a side port. Burbank teaches two different embodiments of a

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biopsy device: with a biopsy cannula (FIG. 14A and 14C) and without a biopsy cannula (FIGS. 6A and 6B). The biopsy device without a cannula is similar in structure to the biopsy device disclosed by Burney : a catheter having a closed distal end (FIGS. 6A and 6B end point 45) and a side port (port 46) adjacent the distal end. Burbank then teaches that a biopsy cannula may be provided on the outside of the device as an alternative mechanism for collecting a biopsy sample (FIG. 14A-14C). Burbank teaches that this biopsy cannula is provided in order to contain the sample within the catheter while the catheter is being withdrawn (Column 18 line 45-Column 19 line 3). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device of Burney with a biopsy cannula, as taught by Burbank, in order to contain the sample within the catheter as it is being moved outside of the body.

Regarding claims 4 and 5, Burney discloses first and second indexing members (Page 19 lines 20-28).

5. Claims 7-10 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 97/28746 to Burney et al. U.S. Patent No. 5,325,587 to Nabai et al.

Burney discloses the claimed invention except for the pledget of absorbable sponge material loaded in the adaptor. Burney discloses that his device may be used to obtain a tissue sample and deliver a composition that includes the use of radiopaque substances (page 23 lines 8-28 and page 26 lines 3-15). Nabai teaches that a sponge is delivered in order to promote healing without the necessity of suturing (Column 3 lines 11-18). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device of Burney with a sponge in order to promote healing in the biopsy location without the need for sutures.

Response to Arguments

6. Applicant's arguments filed September 29, 2003 have been fully considered but they are not persuasive.

7. In response to applicant's argument that Burney et al. does not disclose an adaptor for hydrating and delivering the pledget to the catheter, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

8. Regarding Burney et al. in view of Nabai et al. '587. Burney discloses using the device to deliver medical substances (page 23 lines 8-28 and page 26 lines 3-25). Nabai teaches that sponges are delivered in medical procedures to promote healing at the surgical site without the use of sutures (Column 3 lines 11-18). The device of Burney could be used to deliver a sponge to the surgical site since Burney may be used to deliver other substances to the surgical site.

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be

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calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica R Baxter whose telephone number is 703-305-4069. The examiner can normally be reached on M-F 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on 703-308-2496. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Jessica R Baxter
Examiner
Art Unit 3731


jrb


MICHAEL J. MILANO
SUPERVISORY PATENT EXAMINER
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